REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1, 2, 4-7, 13, 14, and 16-20 were pending in this application when last examined and stand rejected.

Claims 4 and 16 were also objected to.

Claims 1, 2, 4-6 and 13 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Claim 7 has been amended to independent form and to incorporate the subject matter of claim 13 (now cancelled). Further support for amended claim 7 can be found in the disclosure, for example, at page 8, lines 10-25 and also in Example 6.

Claims 13, 14 and 16-20 are amended to change their dependency to claim 7.

Other minor editorial revisions have been made to the claims to better conform to U.S. claim form. Such revisions are non-substantive and not intended to narrow the scope of protection.

Further support for amended claim 16 can be found in the disclosure, for example, at page 9, line 23.

Claim 20 has also been amended to correct a typographical error in the listings of the ingredients in Markush form. Support can also be found in the disclosure, for example, at page 10, lines 2-5.

Claims 7, 14, and 16-20 are pending upon entry of this amendment.

Applicants are submitting the present Amendment without prejudice to the subsequent prosecution of claims to some or all of the subject matter which might be disclaimed by virtue of this response (although none is believed to be), and explicitly reserve the right to pursue some or all of such subject matter, in Divisional or Continuation Applications.

Applicants thank the Examiner for the careful examination of this case and respectfully request reexamination and reconsideration of the case, as amended. Below Applicants address the rejections in the Office Action and explain why the rejections are not applicable to the pending claims as amended.

II. CLAIM OBJECTIONS

Claims 4 and 16 were objected to for the reasons in item 2 on page 2 and item 4 on page 5 of the Office Action.

The present amendment overcomes this objection by cancelling claim 6 and amending claim 16 to change "0.05" to "0.005" as suggested by the Examiner. The amended language is supported by the disclosure at page 9, line 23.

The present amendment also removes the concern in item 5 by changing "N is an integer" to "n is an integer" in claim 13 as suggested by the Examiner.

Withdrawal of the objections is therefore requested.

III. WRITTEN DESCRIPTION REJECTION

Claim 7 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in item 3 on pages 3-5 of the Office Action. This rejection is respectfully traversed.

On page 4 of the Office Action, it is indicated that "the specification fails to disclose a method for increasing lipolysis in adipocytes, comprising administering to a subject in need thereof an effective of amount of composition according to claim 13, because claim 7 is directed to *in vivo* treatment while the support Applicant cites and Example 6 are directed to *in vitro*." The Office notes that the examples in the disclosure are *in vitro* in nature, as opposed to *in vivo*, and that there is no pharmaceutical formulation actually administered to a subject in need of treatment thereof. The Office argues there is no *in vivo* showing for the effectiveness of the method for increasing lipolysis in adipocytes.

Based on these arguments, it appears the Office has confused the enablement and written description requirements by arguing that there is no *in vivo* showing for the effectiveness of

the method for increasing lipolysis in adipocytes. This is an improper basis for a written description rejection. There is no legal requirement to have an actual reduction to practice (or in this case an *in vivo* demonstration) to satisfy the written description requirement.

The test for sufficiency of written description is whether the disclosure reasonably conveys to the artisan that the inventor had possession at the time of filing of the subject matter which is claimed. M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2163, I, 2100-159, 1st column, 2nd paragraph.

This test may be satisfied by: (1) a reduction to practice; (2) a reduction to drawings/chemical formulas; (3) a disclosure of relevant identifying characteristics, such as structure or other physical and/or chemical properties, to sufficiently describe the claimed invention in full, clear, concise and exact terms; (4) a disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure; (5) a sufficient description of a representative number of species; or (6) a combination of the above, sufficient to show the inventors were in possession of the invention. M.P.E.P. (Eighth Ed., Rev. 6 (September 2007) at § 2163,II, A, 3a(i)-(ii).

It should be sufficient that specification describes methods of applying the composition to a subject for the purpose

of increasing lipolysis in adipocytes. It is believed that the specification clearly do this.

For instance, the specification at page 8, lines 15-25 and in Example 6 clearly discloses administering the peptide to increase lipolysis in adipocytes. The specification also clearly discloses that a pharmaceutical, cosmetic, or dermatological composition containing said peptide can be ingested, injected, applied to the skin, hair, nails or mucous membranes. See, for instance, the paragraph bridging pages 9 and 10 of the disclosure. The specification also the composition can take the form of creams, lotions, milks, serums, ointments, shampoo, gel, paste, and foam. See the second paragraph on page 10. The specification on page 11 also discusses in detail how the composition can be administered to subject.

Further, Applicants have amended claim 7 to remove the "in need of treatment thereof" language. As such, amended claim 7 is directed to a method of increasing lipolysis in adipocytes comprising administering to a subject an effective amount of a composition comprising, in an acceptable medium, as an active ingredient, at least a peptide of formula (I): (AA)n-Arg-Gly-Ser-(AA)n.

Applicants respectfully submit that such description constitutes at least a disclosure of relevant identifying characteristics, such as structure or other physical and/or chemical properties, to sufficiently describe the claimed

invention in full, clear, concise and exact terms, and a disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure, to show the inventors were in possession of a method of increasing lipolysis in adipocytes by administering the peptide of formula (I) to a subject. Again, there is no need to have an actual reduction to practice in order to satisfy the written description requirement.

For these reasons, it is believed that one of skill in the art, upon reading the disclosure and in view of the knowledge in the art, would reasonably believe Applicants were in possession of the method of amended claim 7. Thus, the written description rejection should be withdrawn.

In addition, Applicants believe the specification enables the full scope of amended claim 7, despite the Office's argument there is no *in vivo* showing for the effectiveness of the method for increasing lipolysis in adipocytes. It is submitted that the specification need not provide an actual *in vivo* reduction to practice to satisfy the enablement requirement.

Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually

achieved. M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2164.02.

Further, contrary to the Office's position, it is accepted that there is no need for an *in vivo* demonstration of effectiveness to enable a method claim. Instead, the Office must look at the relevant evidence as a whole, and determine if there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity. A rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence. M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2164.02.

In the instant case and as acknowledged by the Office, the specification (e.g., page 8, lines 15-25) defines the triglyceride-lipase activity as well as lipolysis and their relationships with respect to the degree of lipolytic activity of the peptide. Example 1 (though *in vitro*) measures how the peptide effects intracellular ATP levels in cells that can differentiate into adipocytes. Examples 2-4 show the effect of the peptide on protein expression, keratin expression, and cell differentiation. Example 5 shows the lipolysis activity of the peptide on adipocytes and Example 6 shows the effect of the peptide on cAMP levels, which is a measure of lipolytic activity. It is belied that these examples demonstrate that the claimed peptide increases lipolytic activity in adipocytes.

It is believed that this disclosure, when coupled with the detailed disclosure of administering pharmaceuticals and cosmetics, clearly enables the skilled artisan to achieve the claimed method even in the absence of an *in vivo* example.

Moreover, the Office has not provided a rationale and/or evidentiary basis as been provided to question the *in vivo* effectiveness of the claimed method. It is well established that in order to make an enablement rejection, the Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (i.e., the Office must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2164.04. Again, no rational basis has been given showing the ineffectiveness of the claimed method.

For these reasons, Applicants respectfully submit that the skilled artisan could practice the fully scope of the amended claims without undue experimentation.

Thus, the above-noted written description rejection should be withdrawn and an enablement rejection should not be applied.

IV. OBVIOUSNESS REJECTION

Claims 1, 2, 4-6, 13, 14, and 16-20 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over LIU et al. taken with HORTIN et al. or WO 2000-77042 for the reasons in item 5 on pages 5-10 of the Office Action.

This rejection is respectfully traversed as applied to the amended claims. For the sole purpose of expediting prosecution and not to acquiesce to the rejection, claims 1, 2, and 4-6 and 13 have been cancelled, and the remaining claims have been amended to change their dependency to new independent claim 7. The rejection falls, because all claims now depend on claim 7, which was not included in this rejection.

For these reasons, the rejection should be withdrawn.

V. CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

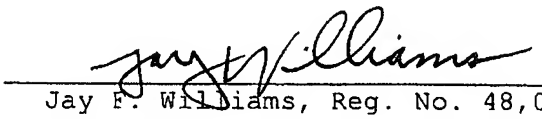
If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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